K080017

SEP 2 6 2008

510(k) SUMMARY

VIDAS® AFP Assay

A. Submitter Information

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Sandra Perreand
Phone Number:	314-731-8594
Fax Number:	314-731-8689
Date of Preparation:	September 18, 2008

B. Device Name

Trade Name:	VIDAS® AFP Assay
Common Name:	Kit, Test, Alpha-Fetoprotein for Testicular Cancer
Classification Name:	Kit, Test, Alpha-Fetoprotein for Testicular Cancer

C. Predicate Device Name

Trade Name:	Tosoh Medical, Inc. ST AIA Pack AFP Enzyme Immunoassay

D. Device Description

The assay principle combines a one-step immunoassay sandwich method with a final fluorescent detection (ELFA). The Solid Phase Receptacle (SPR), a pipette tip-like device, serves as the solid phase as well as the pipetting device for the assay. The assay reagents are ready-to-use and pre-dispensed in the sealed reagent strips (STRs).

All of the assay steps are performed automatically by the VIDAS instrument. The sample is transferred into the well containing AFP antibody (conjugate) labeled with alkaline phosphatase. The sample/conjugate mixture is cycled in and out of the SPR several times. This operation enables the antigen to bind with the immunoglobulins fixed to the interior wall of the SPR and to the conjugate to form a sandwich. Unbound compounds are eliminated during washing steps.

Two detection steps are performed successively. During each step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone) the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is proportional to the concentration of antigen present in the sample.

At the end of the assay, results are automatically calculated by the VIDAS instrument in relation to two calibration curves corresponding to the two detection steps stored in memory, and then printed out.

E. Intended Use

VIDAS® AFP is an automated quantitative test for use on the VIDAS instruments for the quantitative measurement of alpha-fetoprotein (AFP) in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS AFP assay is indicated for the quantitative measurement of Alpha-Fetoprotein (AFP) in serum to aid in the management of patients with nonseminomatous testicular.

F. Technological Characteristics Summary

A general comparison of the similarities and differences of the VIDAS AFP assay to the predicate device is presented in the table below.

Item	VIDAS® AFP Assay	TOSOH ST AIA-PACK AFP (K023894)
General Comparison		
Intended Use	VIDAS® AFP is an automated quantitative test for use on the VIDAS instruments for the quantitative measurement of alpha-fetoprotein (AFP) in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS AFP assay is indicated for the quantitative measurement of Alpha-Fetoprotein (AFP) in serum to aid in the management of patients with nonseminomatous testicular carcinoma.	ST AIA-PACK AFP is designed for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of Alpha-Fetoprotein (AFP) in serum to aid in the management of patients with nonseminomatous testicular carcinoma.
Specimen	Serum	Serum
Antibody	Two mouse monoclonal AFP antibodies	Two mouse monoclonal AFP antibodies
Assay Principle	Two antibody "sandwich" binding of AFP. One antibody is bound to a solid phase and the second antibody is in liquid form and is labeled with fluorescent compound	Two antibody "sandwich" binding of AFP. One antibody is bound to a solid phase and the second antibody is in liquid form and is labeled with fluorescent compound
Automated	Yes	Yes
Assay Technique	Enzyme-linked fluorescent assay (ELFA)	Two-site immunoenzymometric assay
Sample Volume	100 µL	25 µL
Traceability/	Master curve for each kit lot and each	Each calibrator lot are traceable

Item	VIDAS® AFP Assay	TOSOH ST AIA-PACK AFP (K023894)
Standardization	calibrator lot are traceable to 1st IS 72/225 International Reference Preparation (IRP)	to 1st IS 72/225 International Reference Preparation (IRP)
Measurement range	0.500 – 400.00 IU/mL Master curve highest calibration point = 400.0 IU/mL	1 – 400 ng/mL (0.83 – 330.6 IU/mL) Highest calibrator = 200 ng/mL (165.3 IU/mL)

G. Performance Data

A summary of the non-clinical and clinical test results is presented below.

Precision

A panel of three samples was assayed in duplicate in 40 different runs (2 runs per day) with two reagent lots using the same VIDAS instrument at three sites. The total variability (%CV) across all sites and across all samples was < 6.77%.

Limits of Detection

The Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) were determined using two kit lots on two VIDAS instruments (one instrument per kit lot). The results are: LoB = 0.178U/mL, LoD = 0.444/mL, and LoQ = 0.444 ng/ml.

Interfering Substances/Drug Interference

In the study, hemoglobin, triglcerides, bilirubin, human albumin, RF, HAMA, and potential drug interferents were added to a human serum pool containing a measured concentration of AFP. No interfering effect was detected for any of the substances tested.

Hook Effect

No hook effect was observed for AFP concentrations up to 242,000 IU/mL.

Dilution/Linearity

Samples with very high AFP results were diluted with VIDAS AFP kit Diluent to evaluate the appropriateness of the diluent and the recommended maximum dilution. The VIDAS AFP diluent may be used to dilute out-of-range samples (>400 IU/mL) up to 1/20 prior to retesting.

Two high titer natural sera and one low titer natural serum are mixed in variable proportions to yield dilutions that cover the assay's full measurement range and the medical decision level (10 IU/mL). The linearity of the assay is 0.500 – 400.00 IU/mL.

Clinical Trial

A clinical trial was conducted to compare the VIDAS® AFP and the TOSOH ST AIA-PACK AFP assays by testing 257 samples with both assays. A Passing and Bablok regression analysis of the 253 samples gave a slope = 1.128 (95% confidence interval = 1.115 to 1.143) and an intercept = - 0.530 (95% confidence interval = -0.658 to -0.416).

H. Conclusion

The VIDAS® AFP Assay is substantially equivalent to the Tosoh Medical, Inc. ST AIA Pack AFP Assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 6 2008

bioMèricux, Inc.
c/o Ms. Sandra Perreand
Senior Director, North American Regulatory Affairs
595 Anglum Road
Hazelwood, MO 63042

Re: k080017
Trade/Device Name: Vidas® AFP Assay
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor associated antigen immunological test systems
Regulatory Class: Class II
Product Code: LOJ
Dated: August 28, 2008
Received: September 2, 2008

Dear Ms. Perreand:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080017

Device Name: VIDAS® AFP

Indications For Use:

VIDAS® AFP is an automated quantitative test for use on the VIDAS instruments for the quantitative measurement of alpha-fetoprotein (AFP) in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS AFP assay is indicated for the quantitative measurement of Alpha-Fetoprotein (AFP) in serum to aid in the management of patients with nonseminomatous testicular carcinoma.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) - K080017